Initial Approval: October 10, 2018
Revised Dates: April 10, 2019

CRITERIA FOR PRIOR AUTHORIZATION

Advanced Medical Hold Manual Review (AMHMR) PA

PROVIDER GROUP Pharmacy
Professional

MANUAL GUIDELINES The following drug requires prior authorization:
New-to-Market-Drugs that are FDA approved and come on the Medicaid drug file/increased use after October 15, 2018.

CRITERIA FOR APPROVAL (Must meet the following):

- Medication must be prescribed for an FDA-approved indication, age, dose, and frequency based on package insert.
- And, must be meet the associated AMHMR PA reference number below for the requested drug:

1. If the new-to-market drug falls into an existing class/category on the preferred drug list (PDL), the drug will be subject to manual case-by-case review using the non-preferred PDL prior authorization (PA) criteria.

2. If the new-to-market drug falls under an existing Step Therapy PA class/grouping, the drug will be subject to manual case-by-case review using the Step Therapy requirements for the compare drug.

3. If the new-to-market drug falls into an existing PDL class and also falls into existing Step Therapy PA class/grouping, the requested medication must meet the Non-preferred PDL PA criteria and the Step Therapy requirements for the compare drug.

4. If there is an existing dosage form of the same chemical drug available, the existing dosage form must be tried first.
    i. Requests for oral, non-solid dosage forms will only be considered for patients who are unable to swallow solid oral dosage forms (i.e. tablets, capsules) due to age $\leq$6 years, dysphagia or presence of a feeding tube.
    ii. If one or more of the preferred agents is a capsule whose contents can be opened and sprinkled into soft food based on package insert recommendations, patients > 1 year of age will be expected to have a trial and failure of the preferred agent(s)'s capsule dosage form unless there is a documented intolerance or contraindication (i.e. dysphagia, feeding tube).

5. If the new product is a racemic mixture, a single enantiomer or diastereomer, or an isomer of an available medication, OR the new product is a prodrug metabolized to the active ingredient in an available medication, OR the new product is an active metabolite of an available medication for the same indication, then the currently available medication for that indication must be tried at maximum tolerated doses for 90 of the last 120 days prior to approval, unless there is a documented intolerance or contraindication.

6. If the new-to-market drug does not fall into any of the above categories and there does not exist at the time of drug approval, the patient must meet all of the following criteria:

    a. The patient must have an inadequate response to two or more medications FDA-approved for the same indication and/or medications that are considered the standard of care for the indication, when such agents exist. Previous treatment trials for the specific indication must be at maximum tolerated doses for 90 of the last 120 days prior to approval, unless there is a documented intolerance or contraindication to two or more agents.

    b. Provider must submit documentation that includes chart notes documenting previous medication therapy trials, outcomes and dates of each trial, as well as the clinical rationale and anticipated therapeutic benefit from the requested medication.

- **When indicated by the State pharmacy team, the FDA-approved indication, age, dose, and frequency, based upon package insert, may be the only criteria required.**

LENGTH OF APPROVAL: Up to 12 months.

Restricted coverage may be for up to 12 months, at which time the State will bring or have brought a request for permanent management, to the PDL Committee or the DUR Board. A New-to-Market PA may be implemented on the FDA approval date or after.

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DRUG UTILIZATION REVIEW COMMITTEE CHAIR	PHARMACY PROGRAM MANAGER DIVISION OF HEALTH CARE FINANCE KANSAS DEPARTMENT OF HEALTH AND ENVIRONMENT
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DATE	DATE